



Levels of Learning About Leukemia by Pediatric Patients

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Abbreviated Abstract

This project developed and tested a first-of-its-kind multimedia CD-ROM program for pediatric patients ages 4 to 11 with acute leukemia (ALL or AML), as well as their parents, siblings, and classmates. Evidence suggests that giving children information about their serious illnesses is beneficial to them, and this program fills a void in educational software for children with leukemia. Children with leukemia, their families and friends, may benefit if they understand the illness, the procedures to diagnose and treat it, ways their behavior can help cope better with their illness.

The visual presentation of complex issues is tailored to user's age, maturity, cognitive developmental level, reading level, and treatment stage. Our study showed that among children in the CD-ROM group, compared with those in the Book group, there was a greater effect on children's feeling of control over their health ($p = .005$), a non-statistically significant yet consistent trend for enhancing 7-11 year-olds' understanding of leukemia, and a decrease in negative coping strategies among 7-11 year-olds. The CD-ROM, *Kidz with Leukemia: A Space Adventure*, is a useful, engaging, and empowering tool for children with leukemia that can serve as a model for developing future educational materials.

Primary Investigator

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Judith K. Jones, MD, PhD, President of The Degge Group, Ltd., is a clinical pharmacologist and pharmacoepidemiologist who is currently affiliated with Georgetown University, George Washington University (Washington, DC), and the University of Michigan School of Public Health Summer Program. Dr. Jones is an internationally recognized expert in the areas of adverse drug reactions and pharmacoepidemiology. She is also a long-time advocate for patient education and wrote one of the first books to empower patients: *Good Housekeeping Guide to Medicines & Drugs* (Hearst Corporation, 1978, 1980). Dr. Jones has had experience with various aspects of multimedia computer interface, including: 1) work with the TIME project using voice-activated videodiscs for educating medical students; 2) development and testing of a voice-activated computer system for a hypertension clinical trial to optimize data collection and reporting (as Co-Investigator on the NIH SBIR grant # R44 47965); and 3) collaboration in development, beta testing and initial marketing of the computerized medical record system (MEDIDOC) in the US, which was originally developed for the

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European market. 4) Dr. Jones served as PI on the NIH SBIR Phase II grant which produced a multimedia educational CD-ROM for children with leukemia, their families, and friends (Kidz with Leukemia: A Space Adventure, SBIR grant CA71271). She also served as PI on both Phases I and II of the NIH SBIR grants that produced and evaluated in a randomized clinical trial a multimedia educational CD-ROM for adolescents with solid tumors (Conquering Cancer Network: Empowering Teens with Tools, Info, and Inspiring Stories aka CCN, SBIR grant CA86686).

Research Team & Affiliations

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Total Budget

\$790,422.00

Research Objectives

The main objective of this project was to develop and test an interactive, multimedia CD-ROM for children with ALL or AML and their family members. Specific Aims included:

- Define requirements of design and content of a multimedia CD-ROM program for children with leukemia and their families.
- Create storyboards and scripts for all modules of the program.
- Develop prototypes as needed for selected modules of the program.
- Develop and test the software for the program.
- Design and develop a users' manual.
- Evaluate the product relative to: use by and acceptability to children, parents, and health care providers; and the effect on children's understanding of routine leukemia treatment procedures, and feelings of health self-determination, as tested using the instruments Event Knowledge and Children's Health Locus of Control, respectively.
- Refine and finalize the CD-ROM based on evaluation by children with leukemia, their families and healthcare providers.



Theory/Hypothesis

- 1: Children with leukemia using the Kidz with Leukemia (KWL) CD-ROM experience a greater increase in feelings of control over their health status than those who receive a commonly used printed educational resource (such as a book, *You and Leukemia*, Baker L, WB Saunders, 1988).
- 2: There is a defined increase in positive coping skills and/or a greater reduction in negative coping skills among children with leukemia using the KWL CD-ROM than among those who receive a commonly used printed educational resource.
- 3: There is a measurable increase in children's understanding of leukemia among children using the KWL CD-ROM than among those who received a commonly used printed educational resource.
- 4: There is greater satisfaction with an interactive CD-ROM about childhood leukemia compared to satisfaction with a commonly used printed educational resource among 4-11 year-old children with leukemia and their parents.

Experimental Design

This was a pre-post design with randomization of child-parent pairs into treatment (CD-ROM - Kidz with Leukemia: A Space Adventure) and control (Book - *You and Leukemia*) groups.

The effectiveness of the media was evaluated relative to providing information, acceptability in terms of usefulness and appeal, and children's health locus of control (i.e., children's feelings of control over their health).

Final Sample Size & Study Demographics

The project was conducted with children and their parents recruited from Georgetown University's Lombardi Cancer Center (Washington, DC), Children's Hospital (Columbus, OH), University of Virginia Medical Center (Charlottesville, VA), Special Love (Winchester, VA), and Pediatric Hematology/Oncology of Northern Virginia (Fairfax, VA).

Forty-one children were enrolled at the beginning of the study. Due to dropouts, 31 child-parent pairs completed pre- and post-tests. Of these, 16 received the CD-ROM, and 15 received the Book. Eighteen girls and 13 boys completed the study. Fourteen children were in the 4-6 year-old group, and 17 were in the 7-11 age group. Most of the participants were Caucasian (N=25; 81%), three were Hispanic (10%), one was African-American (3%), one was Asian (3%), and one was Other (3%). Nine of these 31 children were off-therapy, whereas the other 22 were undergoing treatment while participating in our study. The percentage of children who had access to a computer at home was 87%.

A total of 32 parents participated, the majority of whom were females (26/32, i.e., 81%). A total of 36 healthcare practitioners responded to the surveys, of whom 15 were nurse practitioners and seven were physicians.

Data Collection Methods

The study was a pre-post design with subjects randomized to one of two treatment levels: the leukemia CD-ROM and a control (the book *You and Leukemia*) which contained analogous information. Randomization was done centrally at The Degge Group. Each interviewer (conducting the interview in person) called a Degge toll-free number to randomize a subject at the beginning of the pre-testing



session. Each subject was assigned an ID, and after the pre-test interview, the subject received the CD-ROM or Book, based on their randomization. Data was collected on a structured instrument. Using only subject ID without identifying information, data was then entered into an Access database for analysis. Approximately 3 months later, the subject was interviewed again – at a post-interview session - using another post-test instrument that was similarly entered into the analytic database. At the post-test session, parents/guardians were also interviewed as to their use and satisfaction with the CD-ROM or Book.

Most interviews were done at the hospital where the child was treated, but occasionally interviews were done at home, especially during post-testing, at the parents' requests.

Criteria for subject selection included:

- Age - 4-11 years,
- Diagnosis - of acute lymphoblastic leukemia or acute myelogenous leukemia,
- Current status - being in first remission, currently being treated, or less than three years since the end of treatment,
- Language skills - ability to understand spoken English,
- Learning skills - absence of a severe learning disability,
- Study participation - a lack of participation in any earlier focus groups about the CD-ROM development, and
- Assent – Assent was required to participate for children 7 years of age and older.

Additionally, parents were required to understand spoken English and, either the child or the parent was required to be able to read materials written in English, should the child be randomly assigned to the control group receiving the commonly used printed material.

Outcome Measures

The intervention's acceptability and use by children with leukemia and their families, specifically with regard to:

- Whether the CD ROM or Book had any effect on children's understanding of their disease or their feelings of self-determination regarding their health;
- What effect the CD-ROM or Book had on children's understanding of their disease and treatment was measured using the Children's Event Knowledge instrument.

The effect the CD-ROM had on children's feelings of control over their health status was measured using the adapted Children's Health Locus of Control instrument:

- Children who completed the Event Knowledge interview also completed a version of a health locus of control scale;
- Children ages 7 to 11 years were asked to complete the 18-item 3-dimensional Children's Health Locus of Control Scale (CHLC);
- Children ages 4 to 6 years were administered the picture version of the CHLC.

The acceptability and use of the interventions were measured using standardized questionnaires; three assessments of acceptability were conducted:

- In the pre-post assessment, at the follow-up interview only, the treatment group of children and parents using the CD-ROM or Book were interviewed to learn frequency of use, who used it, time spent, and acceptability and availability preferences;



- Small (n=5-6) focus groups of children with leukemia and/or siblings in the 2 age ranges at the Washington, D.C., UVA, and Ohio sites were recruited to provide a one-time evaluation, similar to the format used in phase I;
- Health care providers from various sites all over the country were interviewed / surveyed relative to acceptability and availability references.

Evaluation Methods

Pre-test and post-test assessments were done using the Leukemia Children's Health Locus of Control (LCHLC), KIDCOPE (Revised), and Leukemia Event Knowledge interview. Additionally, Satisfaction and Use Questionnaires were administered during post-testing. Four research assistants collected data from these subjects.

Research Results

The most notable results presented in detail in Dragone et al, 2002¹ included:

- (1) Children who received the CD-ROM as compared to those randomized to the Book had a significantly higher increase in LCHLC score from baseline in both age groups; thus, they experienced greater feelings of control over their health status than those who were randomized to the Book group; and
- (2) Overall satisfaction with the use of CD-ROM technology to learn about leukemia among all users, with the most positive response among 4-6 year-olds. Children used the Book for shorter and less frequent periods of time than did those using the CD-ROM.

Barriers & Solutions

The primary barrier was achieving an adequate sample of eligible children with leukemia for participation. While every effort was made to recruit patients at several sites, including leukemia camps, due to several characteristics of this population (e.g., intermittent cancer treatment) it was very difficult to obtain commitment for the duration of the study. This was addressed by broadening the recruitment effort to more sites than originally planned.

Product(s) Developed from This Research

Kidz with Leukemia: A Space Adventure